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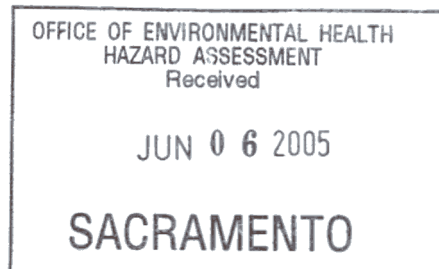
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June 6, 2005

VIA FACSIMILE & U.S. MAIL

**Dr. Joan Denton
Office of Environmental Health Hazard Assessment
1001 I St., 19th floor
Sacramento CA 95814
Fax: (916) 327-1097**

**RE: "Potential Regulatory Action" Under Proposition 65
for "Cooked" Foods (Extended Comment Notice Dated 5/27/05)**

Dear Director Denton:

We represented the plaintiffs in the most important early litigation over the scope of the state's powers to regulate under Proposition 65, AFL-CIO et al. v. Deukmejian et al. (Sacramento Superior Court, No. 502541, filed 5/31/88; complaint attached as Exhibit A) (commonly known as "*Duke II*"). That case settled in 1992 with a binding commitment from the State of California that it would:

1. repeal the illegal regulation that plaintiffs challenged in *Duke II*, which categorically exempted foods from Proposition 65 under some circumstances, and
2. not enact any similar categorical exemption from Proposition 65 at any time in the future, for foods or anything else.

A copy of the settlement agreement is attached as Exhibit B, and we explain its exact language and context below.

The *Duke II* settlement agreement is still binding today. It commits the State to a chemical-by-chemical, science-based approach to regulatory exemptions affecting foods. The “potential regulatory action” for “cooked” foods, which was the subject of your May 9 workshop and your May 27 notice extending the public comment period, is completely contrary to that commitment and would clearly violate the legal principle that the State and your office bound themselves to in that settlement. We explain in more detail below. One purpose of this letter is to remind you, your counsel, and the Attorney General of the State’s continuing legal obligation to comply with the terms of the *Duke II* settlement agreement.

Also, in our nearly 20-year experience with Proposition 65, we have had extensive experience with the litigation and lobbying efforts by certain high-profile organizations claiming to represent the food industry, usually coordinated through trade associations in Washington, D.C., to avoid having Proposition 65 apply to foods. In their many different guises, those efforts have consistently been characterized by gross exaggeration, outright misstatement, and heavy political influence. The current effort to exempt “cooked” foods from Proposition 65 coverage bears the same hallmarks of heavy political pressure and lighter-than-air reasoning – one more attempt to put muscle over mind. Another purpose of this letter is to remind you of the historical context for this current effort, and how little credibility those lawyers’ and lobbyists’ complaints and predictions about Proposition 65’s impact on food products have earned over that long period. They have cried “Wolf!” many times about Proposition 65, beginning before the law even went into effect, and experience has always proven them wrong. We urge you to keep this long history in mind as you address its latest concerns over high levels of known carcinogens in popular food products.

IMPACT OF DUKE II SETTLEMENT ON POTENTIAL REGULATION FOR “COOKED” FOODS

The State of California agreed to the *Duke II* settlement after the Superior Court issued a preliminary injunction against the State, stopping it and your predecessor from going forward with the challenged regulation. In effect, the State conceded that plaintiffs and the Court were right that it did not have the power to exempt foods (or other products) from Proposition 65 coverage by declaring whole categories of exposures exempt, and that the law required a particularized, scientifically based approach to any regulatory exemption. In fact, the State’s legal and administrative representatives conceded this to us personally, shortly after the court ruling. The case would have settled much earlier (and at much lower cost to the state), if it had not been for the private trade association participants’ strenuous opposition to conceding that categorical exemptions for foods were illegal, which continued for years after the State had informally reached that conclusion.

The future commitment by the State in the *Duke II* settlement states:

13. Defendants [the Governor of California and the Director of OEHHA] agree that any provision which is adopted after the date of this agreement to define the term "no significant risk" of the Act [Proposition 65] for any food, drug, cosmetic or medical device product, and which employs standards derived from existing state or federal law shall be based upon specific numeric standards for the chemical, as evidenced by the rulemaking file. Such levels shall be consistent with and confirm to sections 12703 and 12721 of title 22 of the California Code of Regulations [risk- and exposure-based criteria].

Settlement Agreement dated 12/23/92 (see Exhibit B).

For the State to identify exposure levels to Proposition 65 chemicals in foods that are exempt from warning requirements, it is obvious that particularized, chemical-by-chemical science is required.

There is no question that foods generically are subject to Proposition 65. There is equally no question that blanket or categorical exemptions from Proposition 65, for foods or any other source of exposure, are not within the state's power to grant, as OEHHA recognizes. See Regulatory Background for Exposures to Proposition 65 Chemicals in Food, p. 1 (attachment to April 8, 2005 notice). This is the principle that was litigated in *Duke II* and that the *Duke II* settlement confirmed. But once again, we are seeing a well-financed lobbying effort to try to create exemption for food products without coming forward with the necessary science.

In trying to find legal room for a categorical exemption where no legal room exists, proponents will undoubtedly argue that the "cooked food" exemption they are supporting does not violate the *Duke II* settlement, because it does not use exactly the same terms that the *Duke II* settlement forbids. The exact language of the *Duke II* settlement forbids any future Proposition 65 regulation defining "no significant risk" levels of exposure on a non-scientific basis. The "potential regulatory action" exempting certain exposures to Proposition 65 chemicals in "cooked" foods does not explicitly use the term "no significant risk." However, it is legally identical for purposes of compliance with the *Duke II* settlement. The proponents' desired exemption would represent a blanket determination, without a scientific basis, that exposures to a potentially wide variety of listed Proposition 65 chemicals, which occur in the context of one large category of consumer products (i.e., "cooked" foods), do not constitute exposures significant enough to require compliance with Proposition 65 warning requirements. It is important to note that the *Duke II* settlement commitment is cast in terms of definition of exempt exposures, because the parties recognized in 1992 that future regulatory definitions of

exempt exposures were of special concern, and that chemical-by-chemical science needed to be required in that process.

Using “cooking” and/or “heat processing” as the basis for a categorical exemption of exposures would be particularly contrary to science, not to mention logic and previous Proposition 65 experience. Not only is there no science to support the notion that exposures to carcinogens formed by “cooking” or “heat processing” represent less significant health risks than other exposures, but the history of Proposition 65 is replete with examples to the contrary. The application of heat is well known as the cause of many significant exposures to Proposition 65-listed chemicals that have received regulatory and enforcement attention, such as lead in ceramicware (which is fired in a kiln), DEHP in baby-bottle nipples and similar products (manufactured with a heating process), automobile exhaust in parking garages, and perhaps most obviously, cigars and pipe tobacco, which were the subject of the very first Proposition 65 enforcement action in 1988. Secondary cigarette smoke has also been the focus of numerous enforcement actions. In these and many other instances, the application of heat either creates, enhances, or creates the medium for major, undeniably significant exposures to known carcinogens and/or reproductive toxins. If food, why not tobacco? Why not diesel exhaust?

The exemption proponents also claim justification for their desired “potential regulatory action” in the exemption for “naturally occurring” chemicals already set forth in regulation. However, current regulation in 22 CCR 12501 already goes as far in that direction as the law allows. It is clearly the **non-natural** creation and enhancement of carcinogen exposure in foods, through deliberate human intervention, that the proponents wish to exempt. Their “naturally occurring” plus “heat processing” rationale would equally well exempt exposure to tobacco smoke, since tobacco’s ingredients are as naturally occurring as any other agricultural product’s, and the application of heat to them is as integral to the resulting human exposure.

If a court is asked to rule on whether the “potential regulatory action” considered in your May 9 workshop violates the terms of the *Duke II* settlement, it will take into account the plain language and context of the *Duke II* settlement itself, and the fact that exposure exemptions without science to back them were the core of the original controversy. It will also take into account the clearly insupportable and self-contradictory explanations for a “cooking”/“heat processing” exemption, showing it to be a ruse rather than a rational regulatory determination. The State of California paid \$800,000 in legal fees to be led down this path by Washington D.C. lobbyists once before. It should not make the same mistake again.

II. BRIEF HISTORY OF PREVIOUS FOOD-IMPACT CLAIMS AND ATTACKS ON PROPOSITION 65

Before Proposition 65 even went into effect in 1988, trade associations claiming to speak for food manufacturers were taking a lead role in trying to avoid the new law with a series of legal, lobbying, and public-relations maneuvers, predicting dire consequences if food products were to be subjected to California warning requirements. In 1987, at workshop-type hearings held by the Health and Welfare Agency, those associations arranged for the Commissioner of the U.S. Food and Drug Administration to testify in Davis, California, in person, that it was unnecessary for California to apply its new law to foods and other FDA-regulated products because FDA regulation guaranteed the absence of carcinogens in food products to a more stringent degree than Proposition 65 would require. The FDA Commissioner testified in support of the food-and-drug exemption regulation, 22 CCR 12713, that was enacted and then successfully challenged in the *Duke II* litigation by the plaintiffs we represented. Dr. Frank Young, the Commissioner, did not explain why, if FDA regulation was so successful in keeping carcinogens out of food, there would be any worry whatsoever about any food product meeting the no-significant-risk requirement of Proposition 65 without any special exemption.

Years later, while the *Duke II* litigation was still pending on appeal, i.e., prior to settlement, the head of a leading trade association, the Grocery Manufacturers of America, testified to a Cal-EPA hearing that none of the food industry's 15,000 separate products in grocery stores would currently require any Prop. 65 warning for carcinogens. The only concern that the GMA official, Mr. Sherwin Gardner, expressed about the food industry's ability to meet Proposition 65 exposure levels in the future was that California might shift to a more stringent risk threshold for carcinogens than U.S. FDA; i.e., more stringent than FDA's claimed one-in-a-million (or 10^{-6}) standard for carcinogen risk. It was unclear from Mr. Gardner's testimony in January 1992 whether his assurance about the lack of carcinogens in food products had been true when Commissioner Young had testified in 1987, and when the *Duke II* litigation had been filed in 1988, or whether it had become true in the intervening years as food manufacturers had adjusted to the prospect of Proposition 65 compliance.

In the meantime, lobbyists in Washington, D.C. were also making exaggerated and false claims to the federal government about Proposition 65's coming impact on the food industry, trying to convince both the President and the U.S. Congress to take action that would preempt Proposition 65 and prevent it from being applied to food products. Before Proposition 65's warning requirements had taken effect, in 1988, working through U.S. Attorney General Edwin Meese in the Reagan Administration, those lobbyists obtained a Cabinet-level review to consider preempting Proposition 65, reporting to the

Dr. Joan Denton
June 6, 2005
Page 6

Reagan Administration's Working Group on Federal Preemption. They then submitted an economic study which concluded that compliance with Proposition 65 by out-of-state food producers would cost "approximately \$200 million per year." However, the Cabinet-level review group in its official findings determined that the submitted estimate "appears to us to *vastly overstate* the potential impact on [food] producers" (emphasis added) – in part, because it ignored the possibility that food producers would apply quality control measures to keep carcinogen exposures under control. The official findings are attached as Exhibit C (Executive Office of the President, "Economic Analysis of Proposition 65," dated December 5, 1988).

Failing with the Reagan Administration, the same lobbyists then took their case to the new Administration of President George H.W. Bush. In December 1988, shortly before the first Bush Administration took office, one of them had an in-person meeting with the incoming White House counsel, C. Boyden Gray, and told him that Proposition 65 would require health warnings on ice cream and orange juice. Mr. Gray discovered shortly afterward that this was not the case. After the first Bush Administration determined that it would not preempt Proposition 65, the same interests persisted in lobbying FDA Commissioner Young to take agency action against Proposition 65, leading to an unusual White House reprimand which noted that "representatives of the various interests involved in California's Proposition 65, and particularly the food industry, are again seeking opportunities to have their case reheard." See Exhibit D (OMB letter dated May 17, 1989).

At the same time, and for nearly every year since Proposition 65 was passed, the same special interests have sought legislation in the U.S. Congress that would effectively preempt Proposition 65's application to food products and/or other products regulated by the FDA. A chart of the highlights of these continuing efforts is attached as Exhibit E. In support of these efforts, their proponents continue to predict dire consequences for the food industry in having to comply with Proposition 65, even as experience has shown otherwise.

This long history, which we summarize very briefly based on our personal knowledge, is important for you and your new administration in California to be aware of, in order to put into context the current claims and legal positions of the proponents of regulatory exemption for cooked foods.

We are submitting a copy of this letter to Ms. Oshita in your office to be included in the comment record. We are also copying your counsel, the Office of the Attorney

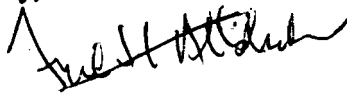
Dr. Joan Denton
June 6, 2005
Page 7

General, and relevant Cabinet officials in the Schwarzenegger Administration. If you would like further information on these subjects, please do not hesitate to contact us.

Sincerely,



David Roe
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San Francisco CA 94111
415-374-8370



Fred H. Altshuler
Altshuler, Berzon, Nussbaum, Rubin & Demain

cc: Terry Tamminen (via regular mail; w/encls.)
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Edward G. Weil (via regular mail; w/encls.)
Cynthia Oshita (for comment record) (via fax to 916-323-8803; w/encls.)✓

Encls.: Duke II complaint (Exhibit A)
Duke II settlement (Exhibit B)
White House "Economic Analysis of Proposition 65" (Exhibit C)
OMB letter to FDA Commissioner (Exhibit D)
Summary of Food Industry Lobbying Attempts [chart] (Exhibit E)

EXHIBIT A



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(List of Counsel appears on following page)

ENDORSED
FILED

MAY 31 1988

JOYCE RUSSELL SMITH, CLERK
By L. BOYKIN, Deputy

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SACRAMENTO

AMERICAN FEDERATION OF LABOR AND)
CONGRESS OF INDUSTRIAL ORGANIZATIONS;)
NATURAL RESOURCES DEFENSE COUNCIL;)
ENVIRONMENTAL DEFENSE FUND; SIERRA CLUB;)
PUBLIC CITIZEN, INC.; CAMPAIGN)
CALIFORNIA; CITIZENS FOR A BETTER)
ENVIRONMENT; SILICON VALLEY TOXICS)
COALITION; AND BERNARDO HUERTA,)

No. 502541

COMPLAINT FOR
DECLARATORY AND
INJUNCTIVE RELIEF

Plaintiffs,

v.

GEORGE DEUKMEJIAN, Governor of the)
State of California; CLIFFORD ALLENBY,)
Secretary, Health and Welfare Agency;)
THOMAS E. WARRINER, Deputy Secretary,)
Health and Welfare Agency,)

Defendant

I.

INTRODUCTION

Plaintiffs AMERICAN FEDERATION OF LABOR AND CONGRESS OF INDUSTRIAL ORGANIZATIONS; NATURAL RESOURCES DEFENSE COUNCIL; ENVIRONMENTAL DEFENSE FUND; SIERRA CLUB; PUBLIC CITIZEN, INC.; CAMPAIGN CALIFORNIA; CITIZENS FOR A BETTER ENVIRONMENT; SILICON VALLEY TOXICS COALITION, and BERNARDO HUERTA bring this action for declaratory and injunctive relief, and by this verified complaint allege that:

1. On November 4, 1986, by an overwhelming majority, the people of California enacted Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986 (hereinafter "Proposition 65" or the "Act."). See Health & Safety ("H & S") Code §25249.5 et seq

2. This complaint is necessary because defendants have thwarted the purposes of Proposition 65 by unlawfully exempting food, drugs, cosmetics and medical devices from the Act's purview.

3. Section 25249.6 of the Act prohibits any person in the course of doing business from knowingly and intentionally exposing an individual to a carcinogen or reproductive toxin contained on the Proposition 65 list of chemicals known to the state to cause cancer (hereinafter "Proposition 65 list") without providing a "clear and reasonable warning to such individual." The Act provides an exception to the warning requirement for carcinogens where "the person responsible can show that the exposure poses no significant risk [of cancer] assuming lifetime exposure at the level in question." §25249.10(c). The Act places the burden of proof of demonstrating the absence of such significant risk on the

1 person responsible for exposure to a carcinogen. Id.

2 4. On February 27, 1988, the day the Act's warning require-
3 ments became effective, defendants promulgated a set of "emergency
4 regulations" providing categorical exemptions from the "no
5 significant risk" provision for carcinogens found in food, drugs,
6 cosmetics, or medical devices so long as they were being used in
7 compliance with various preexisting state and federal laws. These
8 exemptions were granted for all such products, across the board,
9 even where no regulatory levels or controls have been set pursuant
10 to such laws, and despite the fact that Proposition 65 was enacted
11 because the People of California believed existing laws regulating
12 carcinogens failed to adequately protect the public health.

13 5. The regulations violate the Act by adopting in toto
14 federal and state "standards" without any factual or scientific
15 basis for concluding that such standards meet the "no significant
16 risk" requirement of Proposition 65 and without regard to the
17 adequacy or effectiveness of such standards to insure that
18 carcinogens found in food, drugs, cosmetics or medical devices do
19 not exceed the level representing "no significant risk" within the
20 meaning of the Act. Many of these standards have an insufficient
21 scientific basis; others are for substances for which no cancer
22 risk assessment has been performed; and many others are for
23 substances for which regulatory levels have never even been
24 established. Defendants' regulations have therefore resulted, and
25 will continue to result, in a serious obstacle to implementation
26 of the Act in a timely and effective fashion.

27 II.

28 PARTIES

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6. Plaintiff American Federation of Labor and Congress of Industrial Organizations (hereinafter "AFL-CIO") is a federation of 90 national and international unions having a total membership of approximately 14 million working men and women with approximately 1.8 million such members that reside, work, and pay taxes in California. The AFL-CIO maintains regional and sub-regional offices in San Francisco and Los Angeles. The purposes of the AFL-CIO include protecting and promoting the interests of members of its affiliated unions, and of working men and women generally, including their interest in a workplace and environment free of exposure to substances that cause cancer or reproductive toxicity. These members are regularly exposed to carcinogens contained on the Proposition 65 list without warning due to defendants' blanket exemptions from the Act.

7. Plaintiff Natural Resources Defense Council (hereinafter "NRDC") is a nonprofit, membership corporation headquartered in New York, New York, with offices in Washington, D.C. and San Francisco, California. NRDC has a nationwide membership of 84,000 members, more than 17,000 of whom reside in California, dedicated to the defense and preservation of the human environment and the natural resources of the United States. These members are regularly exposed to carcinogens contained on the Proposition 65 list without warning due to defendants' blanket exemptions from the Act. Among the purposes of NRDC is monitoring and participating in government agency decisionmaking to ensure that state statutes designed to protect public health and the environment, such as Proposition 65, are fully and properly implemented. NRDC also engages in independent factfinding and research and regularly

1 distributes to its members and the general public information on
2 matters of environmental concern.

3 8. Plaintiff Environmental Defense Fund (hereinafter "EDF")
4 is a national not-for-profit membership organization established
5 in 1967 and dedicated to the protection and rational use of
6 natural resources, and to the preservation and enhancement of the
7 human environment. Under EDF's incorporation papers and by-laws,
8 EDF and its staff of scientists, lawyers, economists and others
9 seek to pursue these goals through scientific research, monitor-
10 ing, and administrative and judicial action. EDF is incorporated
11 under the laws of the State of New York and has offices and
12 resides in Oakland, California; New York, New York; Washington,
13 D.C.; Boulder, Colorado; Richmond, Virginia; and Raleigh, N.C.
14 EDF has approximately 60,000 members nationwide, of whom ap-
15 proximately 8,000 are residents of California. These members are
16 regularly exposed to carcinogens on the Proposition 65 list
17 without warning due to defendants' blanket exemptions from the
18 Act.

19 9. Plaintiff Sierra Club is a nonprofit, membership corpora-
20 tion organized and existing under the laws of the State of
21 California and having its principal place of business in San
22 Francisco, California. The Sierra Club is a national conservation
23 organization with approximately 400,000 members, approximately
24 155,000 of whom reside in the State of California. These members
25 are regularly exposed to carcinogens on the Proposition 65 list
26 without warning due to defendants' blanket exemptions from the
27 Act.

28 10. Plaintiff Public Citizen is a nonprofit, public

1 interest organization with approximately 55,000 members, ap-
2 proximately 14,000 of whom reside in California. Public Citizen
3 and its Health Research Group have, during the past 15 years,
4 filed numerous petitions and lawsuits charging that the Food and
5 Drug Administration and other federal agencies have not adequately
6 protected the public from substances that pose a risk to human
7 health. Public Citizen's members who live in and visit California
8 are regularly exposed to carcinogens contained on the Proposition
9 65 list without warning due to defendants' blanket exemptions from
10 the Act.

11 11. Plaintiff Campaign California is a nonprofit, statewide
12 grassroots citizen organization dedicated, inter alia to the
13 protection of the environment and especially its drinking water.
14 Campaign California's principal place of business is in Los
15 Angeles, California, and its members are regularly exposed to
16 carcinogens on the Proposition 65 list without warning due to
17 defendants' blanket exemptions from the Act.

18 12. Plaintiff Citizens for a Better Environment (hereinafter
19 "CBE") is a California nonprofit, tax exempt organization under
20 state and federal law with offices in San Francisco, Los Angeles,
21 Berkeley and Santa Cruz and 20,000 members throughout California
22 who are regularly exposed to carcinogens contained on the Proposi-
23 tion 65 list without warning due to defendants' blanket exemptions
24 from the Act. The specific purpose of CBE is to conduct educa-
25 tion, research, litigation, fund raising, and advocacy promoting
26 the protection of the environment and public health.

27 13. Plaintiff Silicon Valley Toxics Coalition is a coalition
28 of organizations and individuals throughout the Silicon Valley

1 formed five years ago to fight toxic pollution in Silicon Valley.
2 In particular, the coalition has been active in combatting ground
3 water contamination and toxic air pollution and in encouraging
4 site clean-up. The Coalition's members are regularly exposed to
5 carcinogens on the Proposition 65 list without warning due to
6 defendants' blanket exemptions from the Act.

7 14. Each of the plaintiffs described in ¶¶ 6 - 13 above
8 brings this action on its own behalf and on behalf of all its
9 members.

10 15. Plaintiff Bernardo Huerta is a resident of McFarland,
11 Kern County, California. He is a farmworker in Kern County. An
12 unusual number of residents in the area in which plaintiff resides
13 have contracted cancer and suffered reproductive problems such as
14 miscarriages and birth defects. Substantial suspicion is focused
15 on toxic chemicals, including substances to which plaintiff is
16 exposed without warning due to defendants' blanket exemptions from
17 the Act. Plaintiff is vitally concerned and fears that toxic
18 chemical exposure may jeopardize his health and that of his
19 children and grandchildren and therefore seeks to ensure that
20 Proposition 65 be fully, quickly, and effectively implemented to
21 diminish any such potential jeopardy.

22 16. Each plaintiff has paid taxes within the past year and
23 therefore brings this action pursuant to Code of Civil Procedure
24 §526a.

25 17. Defendant George Deukmejian is Governor of the State of
26 California and is charged with implementation of Proposition 65.
27 Plaintiffs are suing Governor Deukmejian in his official capacity.

28 18. Defendant Clifford Allenby is Secretary of the Health

and Welfare Agency and is sued in that capacity. The Agency has been designated by the Governor as the lead agency for implementation of Proposition 65.

19. Defendant Thomas E. Warriner is the Undersecretary and General Counsel of the Health and Welfare Agency. The Agency is the lead agency within the meaning of H & S §25249.12, and the regulations challenged here were adopted by defendant Warriner.

III.

CAUSE OF ACTION FOR DECLARATORY AND INJUNCTIVE RELIEF

20. Plaintiffs refer to and incorporate by reference as if specifically set forth herein paragraphs 1 - 19, inclusive.

21. One of the principal purposes of Proposition 65 is to increase the public's protection from toxic substances by requiring that clear and reasonable warning be given prior to exposure to a listed carcinogen, unless the person responsible can demonstrate that such exposure poses "no significant risk." Thus, for any chemical published on the Proposition 65 list, H & S §25249.6 expressly prohibits any "person in the course of doing business" from knowingly and intentionally exposing any individual to such a chemical "without first giving clear and reasonable warning to such individual, except as provided in Section 25249.10." This requirement becomes effective for any particular chemical twelve months after it is placed on the Proposition 65 list, and is now in effect for 29 listed chemicals and will later be in effect for more than 200 chemicals already listed.

22. H & S §25249.10(c) provides that no warning under the Act is necessary for:

An exposure for which the person responsible can show that the exposure poses no significant risk

1 assuming lifetime exposure at the level in question for
2 substances known to the state to cause cancer...based on
3 evidence and standards of comparable scientific validity
4 to the evidence and standards which form the scientific
5 basis for the listing of such chemical pursuant to
6 subdivision (a) of Section 25249.8. In any action
7 brought to enforce Section 25249.6, the burden of
8 showing that an exposure meets the criteria of this
9 subdivision shall be on the defendant.

10 23. On February 27, 1988, defendant Warriner adopted a set
11 of emergency regulations, set forth at 22 California Code of
12 Regulations "CCR" Division 2, Chapter 3, that allow exposure
13 without warning to substances covered by Proposition 65 on the
14 sole basis that such substances are in conformity with pre-
15 existing state or federal regulatory schemes.

16 24. By letters dated January 26, 1988 and February 29, 1988,
17 plaintiffs informed defendant Warriner that regulations allowing
18 automatic exemptions based on pre-existing state and federal law
19 violate Proposition 65.

20 25. Defendants' regulation contained in 22 CCR §12713,
21 provides, inter alia, categorical exemptions for exposures to
22 listed chemicals known to the state to cause cancer that are
23 present in food, drugs, medical devices or cosmetics. These
24 exemptions are granted for all such products in a wholesale,
25 across-the-board fashion whenever their use is in conformity with
26 various state and federal laws and regulatory standards. 22 CCR
27 §12713(c)(1)-(8). In addition, these exemptions are granted for
28 all such products even where they contain carcinogens for which no
regulatory standards have been set by either the state or federal
governments. 22 CCR §12713(d).

26 26. In adopting these regulations, defendants failed to
conduct a case-by-case study or otherwise determine whether state

and federal standards for the over 200 chemicals currently on the Proposition 65 list were adequate to insure "no significant risk" of cancer from exposure to such chemicals in food, drugs, chemicals or medical devices. Contrary to the purposes of the Act, defendants adopted pre-existing federal and state standards in toto without sufficient evidentiary basis for their action.

27. The state and federal standards adopted pursuant to the statutory schemes incorporated in 22 CCR §12713 do not in fact in all cases prevent "significant risk" of cancer. These standards are inadequate because they allow exposure in excess of "no significant risk" even under defendants' own regulatory definition of that term (22 CCR §12711), because they lack a sufficient scientific basis, and because they include numerous instances in which the government has simply failed to regulate carcinogens-- i.e., there are no regulatory levels at all.

28. By providing in 22 CCR §12713 for automatic exemptions from the "no significant risk" requirement based upon conformity with various state and federal laws -- including statutory schemes pursuant to which the state and federal governments have failed to set regulatory levels -- defendants have violated the Act.

29. By adopting 22 CCR §12713 which frustrates rather than furthers the purposes of the Act, defendants have violated §25249.12 of the Act.

30. As a result of defendants' blanket exemptions, plaintiffs, their members and all California residents are suffering and will continue to suffer irreparable injury through involuntary exposure to chemicals known to cause cancer in food, drugs, cosmetics and medical devices without a clear and reasonable

1 warning as required by the Act. Plaintiffs and their members are
2 further harmed in their capacity as California taxpayers by
3 defendants' expenditure of public funds in the unlawful ad-
4 ministration of Proposition 65.

5 31. Defendants' actions have created a true and actual
6 controversy between the parties entitling plaintiffs to declara-
7 tory relief under CCP §1060.

8 32. Plaintiffs have no plain, speedy, or adequate remedy, in
9 the ordinary course of law.

10 WHEREFORE, plaintiffs pray:

11 1. That the Court issue a declaratory judgment declaring
12 that 22 CCR §12713 or any similar regulation that interprets
13 Proposition 65 as providing an automatic exemption from the "no
14 significant risk" requirement based upon conformity with other
15 federal or state laws is unlawful; and

16 2. That the Court issue a preliminary and permanent injunc-
17 tion restraining defendant George Deukmejian, Governor of the
18 State of California, defendant Clifford Allenby, Secretary, Health
19 and Welfare Agency, and defendant Thomas E. Warriner, Deputy
20 Secretary, Health and Welfare Agency, their successors in office,
21 agents, employees, and all persons acting by, through, under, or
22 in concert with them, from enforcing Title 22 CCR §12713 and from
23 promulgating any similar regulation that interprets Proposition 65
24 as providing an automatic exemption from the "no significant risk"
25 requirement based upon conformity with other federal or state
26 laws; and

27 ///

28 ///

1 3. That the Court grant plaintiffs their costs and reason-
2 able attorneys' fees incurred in this proceeding and such other
3 relief as the Court deems just and proper.

4 Dated: May 31, 1988.

5 Respectfully submitted,

6 STEPHEN P. BERZON
7 GAY C. DANFORTH
8 Altshuler & Berzon

9 LAURENCE GOLD

10 ALBERT H. MEYERHOFF
11 Natural Resources Defense Council

12 DAVID B. ROE
13 Environmental Defense Fund

14 RALPH SANTIAGO ABASCAL
15 California Rural Legal Assistance

16 WILLIAM B. SCHULTZ
17 Public Citizen, Inc.

18 BY: 

19 Stephen P. Berzon

20 BY: 

21 Albert H. Meyerhoff

22 BY: _____

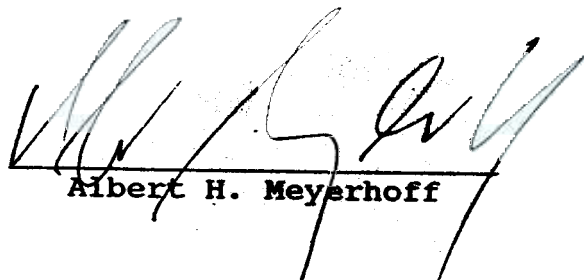
23 David B. Roe

VERIFICATION

I, Albert H. Meyerhoff, am the attorney for plaintiffs Natural Resources Defense Council; Sierra Club; Campaign California; Citizens for a Better Environment; and Silicon Valley Toxics Coalition in this action; I am more familiar with the facts alleged in the complaint than are plaintiffs; the foregoing complaint is true of my own knowledge.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: May 31, 1988



Albert H. Meyerhoff

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25 Attorney for Bernardo Huerta
26
27
28

EXHIBIT B

SETTLEMENT AGREEMENT

1. This agreement is entered into between the AMERICAN FEDERATION OF LABOR AND CONGRESS OF INDUSTRIAL ORGANIZATIONS, the NATURAL RESOURCES DEFENSE COUNCIL, the ENVIRONMENTAL DEFENSE FUND, the SIERRA CLUB, PUBLIC CITIZEN, INC., CAMPAIGN CALIFORNIA, CITIZENS FOR A BETTER ENVIRONMENT, SILICON VALLEY TOXICS COALITION, BERNARDO HUERTA, herein referred to as "Plaintiffs", and PETE WILSON, Governor of the State of California, and CAROL J. HENRY, Ph.D., Director of Environmental Health Hazard Assessment for the State of California, herein referred to as "Defendants".

2. Plaintiffs and Defendants are engaged in a legal action entitled American Federation of Labor and Congress of Industrial Organizations, et al., v. George Deukmejian, Governor of the State of California, et al. Defendants are successors in interest by law to former Governor George Deukmejian, former Secretary of Health and Welfare Clifford Allenby, and Health and Welfare Undersecretary Thomas E. Warriner, the original named defendants in this action.

3. Plaintiffs filed their complaint for declaratory and injunctive relief on May 31, 1988, in Superior Court of the State of California in and for the County of Sacramento (Case no. 502541). The complaint sought judicial invalidation of an emergency regulation adopted by Defendants on February 16, 1988 and subsequently adopted through formal rulemaking. This regulation is found at section 12713 of title 22 of the California Code of Regulations, and is herein referred to as the "regulation".

4. On April 16, 1990, the Sacramento Superior Court entered judgment, granting Plaintiffs' motion for summary judgment and declaring the regulation null and void. Defendants filed an appeal in the Court of Appeal for the Third Appellate District (3 CIVIL C 008697).

5. Plaintiffs contend that the regulation illegally adopts a categorical exemption from the Safe Drinking Water and Toxic Enforcement Act of 1986 (Health and Safety Code section 25249.5, et seq.) (herein referred to as the "Act") for food, drug, cosmetic and medical device products.

Initials:

PH
CH
TH

6. Defendants contend that the regulation validly adopts standards drawn from other state and federal law to determine compliance with the Act. By executing this agreement, neither Plaintiffs nor Defendants concedes their position on the validity or invalidity of the regulation. Nothing in this agreement shall be construed as an admission by either party as to the validity of any contention made by the other.

7. Plaintiffs and Defendants resolve by this agreement all aspects of the litigation identified in paragraphs 2, 3, and 4 in the interest of avoiding the further expenditure of legal and technical resources.

8. Plaintiffs and Defendants agree that the judgment of the trial court dated April 16, 1990, shall have no res judicata or collateral estoppel effect in any enforcement action taken pursuant to the Act.

9. Defendants will create a "Priority List of Chemicals for Carcinogenic Dose-Response Assessment", herein the "Priority List", which will assign dose-response assessment priority for all chemicals listed pursuant to Health and Safety Code section 25249.8 as "known to the state to cause cancer" for which there is no level provided in section 12705 of title 22 of the California Code of Regulations. The initial Priority List shall assign high priority to the following substances:

Benz[a]anthracene
Benzo[b]fluoranthene
Benzo[j]fluoranthene
Benzo[k]fluoranthene
Benzotrichloride
Dibenz[a,h]acridine
Dibenz[a,j]acridine
7H-Dibenzo[c,g]carbazole
Dibenzo[a,e]pyrene
Dibenzo[a,h]pyrene
Dibenzo[a,i]pyrene
Dibenzo[a,l]pyrene
Diepoxybutane
Diethyl sulfate
3,3'-Dimethoxybenzidine (ortho-Dianisidine)
3,3'-Dimethylbenzidine (ortho-Tolidine)
Hexamethylphosphoramide

Initials: 


Indeno [1,2,3-cd]pyrene
Lead phosphate
5-Methylchrysene
Methyl iodide
5-(Morpholinomethyl)-3-[(5-nitro-furfurylidene)-amino]-2-oxalolidinone
Nickel carbonyl
4-Nitrobiphenyl
2-Nitropropane
N-Nitrosomethylvinylamine
N-Nitrososarcosine
Polygeenan
Saccharin, sodium

10. Defendants will further establish a process to update the priority list, based upon input from interested parties, on a quarterly basis concurrent with the issuance of each revision of the Governor's list of chemicals known to the state to cause cancer to reflect new chemical listings, completed dose-response assessments, and public input.

11. Defendants will schedule dose-response assessments in order to develop "no significant risk" levels for inclusion in section 12705 for approximately 30 substances assigned high priority on the priority list, with a target date of July 1, 1993 for development of the levels. These chemicals may include the substances identified in paragraph 9, or such other chemicals as Defendants deem necessary for the protection of the public health or for orderly implementation of the Act.

12. Defendants agree to repeal the regulation, effective July 1, 1993. Failure by Defendants to develop or adopt all of the "no significant risk" levels referred to in paragraph 11 shall not delay the repeal of the regulation.


13. Defendants agree that any provision which is adopted after the date of this agreement to define the term "no significant risk" of the Act for any food, drug, cosmetic or medical device product, and which employs standards derived from existing state or federal law shall be based upon specific numeric standards for the chemical, as evidenced by the rulemaking file. Such levels shall be consistent with and conform to sections 12703 and 12721 of title 22 of the California Code of Regulations.

Initials: 

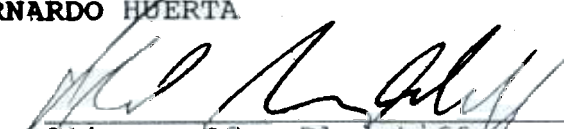
Settlement Agreement
Page 4

14. Defendants agree to pay Plaintiffs' attorney fees in the amount of \$800,000. The fees shall be paid under Code of Civil Procedure section 1021.5 and only out of the state budget appropriations made expressly for that purpose (Item No. 9810-001-001). Plaintiffs agree that payment of the amount specified in this paragraph shall constitute a full and final satisfaction of all claims for attorney fees and costs arising out of the litigation which is identified in paragraphs 2, 3, and 4 of this settlement agreement. Plaintiffs agree to enter between themselves an agreement dividing the amount specified among themselves as they deem appropriate. A claim may then be submitted to the State Controller for payment of the fees. In making such claim, Plaintiffs agree to execute any such release or releases as may be required by the Office of the State Controller.

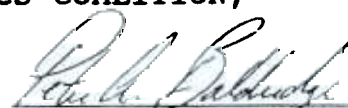
15. The terms of this settlement agreement may be enforced by any party through an appropriate judicial proceeding.


John J. Zelnick
Attorney for Plaintiffs
AMERICAN FEDERATION OF LABOR AND
CONGRESS OF INDUSTRIAL ORGANIZATIONS,
the ENVIRONMENTAL DEFENSE FUND, and
BERNARDO HUERTA

Date: December 23, 1992


Michael A. Kelly
Attorney for Plaintiffs
NATURAL RESOURCES DEFENSE COUNCIL,
SIERRA CLUB, PUBLIC CITIZEN, INC.,
CAMPAIGN CALIFORNIA, CITIZENS FOR A
BETTER ENVIRONMENT, SILICON VALLEY
TOXICS COALITION,

Date: December 23, 1992

By: 
Robert L. Babbidge
Attorney for Defendants

Date: December 23, 1992

EXHIBIT C

EXECUTIVE OFFICE OF THE PRESIDENT

COUNCIL OF ECONOMIC ADVISERS

WASHINGTON, D.C. 20500

December 5, 1988

ECONOMIC ANALYSIS OF PROPOSITION 65

Submitted by the Working Group on the Economic Costs of Proposition 65 to the Working Group on Federal Preemption

Summary of Analysis

This Working Group has attempted to assess the magnitude of the economic costs that have been or are likely to be imposed upon persons outside of California by that state's Proposition 65. Only if significant costs are borne by non-Californians can we justify recommending preemption. Our conclusion is that the law to date has imposed only relatively minor costs upon non-California persons. Unfortunately, there is not yet sufficient data available to offer an accurate estimate of the magnitude of those costs.

The implementation of this law is in a relatively early stage, and it is possible that over time, as the structure of implementing regulations is more fully articulated, and as affected companies make the adjustments needed for compliance, more substantial burdens on interstate commerce will result, perhaps in quite sudden fashion. We therefore recommend that the conclusions of this Working Group be periodically reassessed by Federal officials as more information becomes available, and that the Federal Government take steps to determine how quickly it could act to preempt the Proposition 65 warning requirements should it become advisable to do so.

Discussion

I. Introduction

Claims have been made by representatives of the food industry, the cosmetics industry, the over-the-counter drug industry, and others that the portions of California's Proposition 65 that relate to the exposure of consumers to carcinogens and reproductive toxins impose a substantial burden on interstate commerce which justifies Federal preemption. This Working Group has attempted to assist in evaluating these claims by ascertaining the economic costs that these provisions of Proposition 65 have imposed on persons outside of California, and by identifying the circumstances under which the law may in the future impose substantial costs upon non-California persons.

Proposition 65 imposes separate and distinct warning requirements for products containing chemicals listed by the state of California as known carcinogens, and for those containing chemicals listed as known reproductive toxins. This analysis will therefore consider separately the economic effects of each of those two requirements.

The Working Group has met with various trade associations, a representative of the Environmental Defense Fund, and representatives of over half a dozen companies. The industry organizations have expressed strong concern as to the impact of Proposition 65. The company representatives almost unanimously asserted that faced with a listed chemical that was unavoidably contained in a product in sufficient concentration, they would choose to label for California alone rather than either label nationally or withdraw from the California market. The California market was viewed by them as too important to abandon.

Given that under those circumstances they would choose to label only a portion of their output, their major concern stemmed from the costs of having to segregate products intended for California distribution from those intended for distribution in the rest of the country. In most cases, their existing distribution systems could not achieve the segregation. They claim, undoubtedly accurately, that their inventory costs would rise as well.

The companies also expressed concern about keeping unlabeled products from being transferred to California, opening them up to potential liability, as well as about the effect on sales of having products labeled for California turn up on the shelves in other states. They were concerned as well with the impact that future law suits claiming their products contained substances causing cancer or reproductive harm would have on their sales.

It should be noted that a potentially significant cost that might result from labeling is that consumers could be misled about risk. Existing products meet Federal standards, and the Proposition 65 labels could lead consumers to believe they are less safe than is in fact the case. If labeled products are sold outside of California, then consumers may switch to unlabeled products which might contain more of the specified chemical than the labeled product. We have not tried to quantify the cost of any misinformation that Proposition 65 may provide, but it could be significant, especially in California. If California's labels interfere with consumers' understanding of Federally required labels describing true risks, preemption may be required. Since no Proposition 65 labels are now being provided, it is premature to consider this issue.

II. Economic Costs Imposed Upon Non-California Persons by the Carcinogen Warning Requirement.

A. Existing economic costs.

The economic costs imposed thus far upon non-California persons by the carcinogen warning requirement appear to be relatively minimal. Interim California regulations exempt all FDA-regulated products from those requirements, and allow the alcoholic beverage warning requirements to be satisfied through the posting of signs on the sale premises. Additional protection is also provided many producers through their participation in a toll-free telephone information system, although this regulation-endorsed system is now subject to court challenge which may well result in its invalidation as a means of sufficient warning. While at least two major California retailers (Safeway and Von's) have publicly announced that they will not post shelf signs for consumer products, and will instead require producers to provide product labels or certification of product compliance, we are not aware of any producer (with the exception of the tobacco companies discussed below) who has either labeled its products with carcinogen warnings, or has withdrawn those products from the California market.

A Proposition 65 lawsuit filed against the cigar and tobacco manufacturers has been recently settled on terms that will require such manufacturers to label all of their California products with carcinogen and reproductive toxin warnings. Indications are that the primarily national-scale producers of such tobacco products intend to incorporate Proposition 65-conforming labels nationwide, so as to avoid incurring substantial segregation of products distribution costs, and thus are likely to incur only minor added label redesign costs.¹

B. Potential future economic costs.

While Proposition 65 has of yet only had minimal impact, it is likely that its impact over time will be more substantial. Several foreseeable future events, if they come to pass, will potentially increase the impact of the carcinogen warning requirements on out-of-state producers. First, the toll-free telephone information system could be judicially determined in pending litigation to provide inadequate warning, an outcome we regard as likely. Second, the interim exemption now available for FDA-regulated products could be superseded by numerical standards for exposure levels for individual chemicals, also a likely prospect. Third, California is likely, over time, to add new chemicals to the carcinogen list, possibly including some commercially important pesticides.

Assuming for the sake of argument that all of the above events occur, the economic impact upon non-California persons will depend upon the producer responses. Assuming further, as

seems reasonable, that most or all producers would choose not to withdraw their products from the significant California market if this can be avoided, they would be forced to choose from among the following options:

1. Implementation of quality control procedures sufficient to assure that all products sold in California do not contain concentrations of any listed carcinogenic chemicals sufficient to require warning labels. This may include monitoring suppliers or even switching sources of supply;
2. Labeling of all products sold anywhere in the U.S. that contain sufficient concentrations of listed carcinogenic chemicals with Proposition 65-conforming warnings; or
3. Labeling of only those products intended for distribution in California, and that contain sufficient concentrations of carcinogenic listed chemicals, and segregation of those products during distribution from those to be distributed elsewhere.

On the basis of discussions with a number of representatives of producer firms or their trade associations, it appears to us that very few products (tobacco excepted) contain levels of listed carcinogens sufficient to require warnings under the numerical exposure standards likely to be imposed by California once the interim exemption for FDA-regulated products is lifted. However, food industry representatives claim that the level set for Dieldrin, a pesticide no longer in use, would require labeling for virtually all products containing fruits and vegetables, as well as for raw produce. Standards for other pesticide compounds may be set quite close to the persistent "background" levels stemming from prior use. Whether the "naturally occurring" exemption is interpreted to cover concentrations resulting from earlier human activity may have a major impact on the burden. The current definition specifies that only chemicals that do not result "from any known human activity other than ordinary cultivation practices" are considered to be "naturally occurring."

California's final exposure standards may well be no more restrictive than current FDA requirements, and may be more lenient than those existing FDA standards by roughly an order of magnitude, although this claim has been strongly disputed by some industry representatives who have argued that issuance by California of exposure standards more stringent than those of Federal law is almost inevitable. The costs imposed by the cancer-warning provisions of the law may be primarily of the nature of product testing and quality control expenditures, rather than what appears to be the more substantial labeling and product segregation outlays.² However, if very stringent exposure standards are in the future applied by California,

particularly to any newly-listed and commercially important pesticides, cancer warning labels may be required for a large number of products, rather than only quality control measures.

These quality control expenditures may prove to be fairly substantial, given the need to test individual product batches for a large number of low-concentration chemicals,³ and given the problems faced by manufacturers of controlling the quality of inputs received from numerous raw material suppliers. As an example of these type of costs, one company has told us that to meet the standard for aflatoxin, a naturally occurring carcinogen, they have given up using certain kinds of peanuts and are spending more on screening the peanuts after purchase. This company asserts that they cannot separate their peanut butter produced for California from that sold elsewhere. That company has spent \$1.2 million in the last few months on ensuring that only peanuts with less aflatoxin are used. They estimate that their ongoing annual costs to meet this California standard will be \$1.5 million. If other companies follow this lead and purchase only peanuts with low levels of aflatoxin, the price of such peanuts will rise while the price of other peanuts fall.

It must be kept in mind that firms now have in place extensive quality control and testing procedures designed to assure compliance with Federal standards. Only the marginal added costs of more comprehensive and/or sensitive procedures sufficient to comply with the Proposition 65 standards are probably attributable to that statute. Even if these marginal added quality control costs are substantial, much or even most of these costs are likely to ultimately be borne by California consumers rather than by either the producers or the non-California consumers of those products. The precise allocation of the costs among these groups depends upon the elasticities of supply and demand in the relevant California product markets,⁴ and upon the degree of competition from producers who do not sell in California that faces national producers in their non-California markets. At this time, there is insufficient information available concerning those parameters to accurately estimate either the total amount of likely marginal added quality control expenditures, or the portion of those expenses that will be borne by non-California persons.⁵

Any quality control measures undertaken are unlikely to be 100 percent effective, and some products sold may subsequently be determined (in litigation) to have contained sufficient levels of carcinogens to require warnings.⁶ Some penalties may consequently have to be paid by producers, and adverse publicity resulting from those lawsuits may injure sales.

To the extent producers instead choose to label products on a nationwide basis--a course of action that appears to us unlikely outside of the tobacco industry, given the realities of marketplace competition with unlabeled products outside of

california--the costs are likely to be minor, consisting only of a one-time label redesign outlay.⁷ If, however, some producers choose to label only those units of products destined for California, and not those destined for sale elsewhere, they may incur substantial added distribution and inventory costs. However, a major portion of those costs are likely to be borne by California consumers, given the relevant California price elasticities, and given the effect of competition in non-California markets in restraining price increases in these markets. Again, the precise allocation of these costs between producers and California consumers depends upon the elasticities of supply and demand in the relevant California markets.

If national producers choose the labeling and segregation option, this will provide a slight advantage for producers who produce only for the California market, and who thus need not incur segregation expenses. However, this cost advantage is likely to be relatively small in magnitude and benefit only a small proportion of the producers.

We have been provided with an economic analysis of the costs of Proposition 65 that was prepared by (research group) ^{for a} national grocery group. That study estimates the total cost of out-of-state 1999 producer compliance with Proposition 65 to be approximately \$200 million per year, and that between 35 percent and 70 percent of that cost will not be shifted forward to California consumers in higher prices, but will instead come out of producer profits.

However, for a number of reasons this estimate appears to us to vastly overstate the potential impact on producers. First, and most importantly, the study assumes that all processed food items will be labeled and segregated from production not destined for California, when in fact many items (for example, meats and shipments to food service establishments) which may total 45 percent of more of all shipments are not even governed by the retail product labeling requirements of Proposition 65. Second, for those products potentially covered by the Proposition 65 labeling requirements, as discussed above most do not contain carcinogen levels sufficient to justify warnings. Third, for those products which may contain sufficient carcinogen levels to require warnings, producers will likely, if it is possible at reasonable cost, utilize better quality control measures rather than more costly labeling and product segregation. Fourth, the demand elasticities estimated by (res. gp.) are presented in misleading fashion so as to suggest higher demand elasticities and less shifting of costs to California consumers than would likely be the case.⁸ Finally, the study attaches undue weight to regression coefficients that suggest only partial cost shifting, when those coefficients are in fact not significantly different (even at the 90 percent significance level) from coefficients which would imply that all costs were shifted to California

consumers. On the whole, the res. op. study must be taken as an unlikely worst-case scenario.

We were also provided with a similar study done by the Research Group B

That study estimated the added costs of Proposition 65 at \$95 million annually. However, that study utilized many of the same unrealistic assumptions used by the Lexecon study regarding the scope of the coverage of Proposition 65, and the likely producer responses. The RGB study did not address the allocation of the cost burden between producers and California consumers.

In estimating the potential cost of Proposition 65 on the rest of the economy under the pessimistic assumption that substantial labeling will be required, it is critically important to accurately estimate the relevant elasticities of demand and supply. The relevant demand elasticity is not that facing an individual producer or seller in California, which may be quite high, but is the generally smaller elasticity of demand facing the importers of the product viewed as a group. Thus, if all the product is produced entirely outside of California, coffee being such an example, the relevant demand elasticity is the industry elasticity, which is estimated by USDA for coffee to be only .19. In such a case, given a reasonable estimate of the industry supply elasticity, say 2 (to be conservative), less than 10 percent of the cost imposed by Proposition 65 would be borne by the suppliers; the remainder would be passed on to California consumers.

In summary, we are of the view that the future costs for food products of the Proposition 65 carcinogen warning requirements are likely to be primarily of the nature of additional quality control expenditures, rather than labeling expenditures, and consequently are likely to be smaller in magnitude, and in any event will be borne in large part by California consumers through higher prices. This conclusion presumes, however, that California does not subsequently list as carcinogens and adopt highly stringent exposure standards for any widely used pesticides.

However, the over-the-counter industry may face more substantial problems. It seems likely that California may list ethanol, aspirin, and saccharin as either carcinogenic or causing reproductive harm. If so, many if not most over-the-counter drugs may be required to be listed. Since many of these preparations come in a multitude of sizes and different forms, labeling and segregation could become quite expensive.

Even if one assumes that substantial numbers of products will require labeling and segregated distribution systems, the costs of Proposition 65 that will be borne by out-of-state producers will only amount to a very small percentage of their

California sales revenues. For example, accepting as accurate (res. gp.) estimates that California annually imports 58.8 billion of processed foods, and that labeling and segregation costs for labeled products will amount to between one and six percent of their sales values, if one arbitrarily assumes that 10 percent of such foods will have to be labeled (probably a high estimate even for the worst case), the total annual cost of labeling and segregation will be between \$8.8 million and \$52.8 million. On average the elasticity of demand for imported foods is -.1, and the elasticity of supply is .2, then one-third of this cost will be borne by out-of-state producers, or roughly \$2.9 million to \$17.6 million, a "tax" on the industry of only about 0.03 percent to 0.2 percent of the value of California sales.

III. Economic Costs for Non-California Persons of the Reproductive Toxin Warning Requirement

A. Existing economic costs.

The economic costs imposed thus far upon non-California persons by the reproductive toxin warning requirement also appear to be relatively minimal. We are not aware of any product that has been labeled with such a warning, or that has been withdrawn from the California market to avoid having to give such a warning. (Although, as discussed above, cigar and pipe tobacco will shortly carry such a warning label.)

B. Potential future economic costs.

There is a potential for substantial economic costs to ultimately result from the reproductive toxin warning requirement. The warning-triggering levels of such toxins are statutorily set at a low level equal to 1/1000 of the "no observable effect level," and no interim exemption is available for FDA-regulated products. The application of this standard to the listed reproductive toxin lead poses special concern, since the warning level standard is so low as to approach "background" environmental levels. The California regulations do provide an exemption for that portion of toxin concentration which was "naturally occurring" in the raw materials, but that exemption is of uncertain scope, may be difficult to establish in practice, and is inapplicable to cosmetics or over-the-counter drug products. An additional potential concern is that aspirin or vitamin A could conceivably be added to the reproductive toxin list. If so, labels would be required for a number of items, since these chemicals' concentrations in products that utilize them far exceed the level requiring a warning label. The addition of certain commercially important pesticides to the list could also lead to labeling of significant numbers of products.

Legislative efforts to amend this statute to introduce flexibility into the application of the reproductive toxin warning requirements have thus far proven unsuccessful, but are

ongoing and have some support from Proposition 65's major environmental group advocates. If those efforts continue to be unsuccessful, it could well be that significant numbers of products would have to be labeled with reproductive toxin warnings on account of their lead concentrations, and perhaps also because of pesticide concentrations. If so, substantial labeling and segregation costs would result. However, again, such costs would be borne to a large extent by California consumers.

V. Conclusions

The Proposition 65 carcinogen and reproductive toxin warning requirements have to date imposed relatively minor costs upon non-California persons. There is a potential, however, for the future costs of those requirements to be substantially higher, the level depending primarily upon the stringency of the numerical carcinogen standards ultimately adopted by California, the nature of any new carcinogens or reproductive toxins subsequently listed, and upon the ability of producers to meet whatever reproductive warning standards are finally imposed upon lead or pesticide concentrations in products. We thus recommend that the application by California of Proposition 65 be monitored by Federal officials on an ongoing basis, and that the conclusions of this Working Group be periodically reassessed as that experience dictates.

In meeting with industry and environmentalists we are hearing conflicting testimony as to the reasonableness of California's risk assessment methods. We were told by some persons that the resulting standards for carcinogens would be less strict than Federal standards, and by other persons that they would be more strict. California has completed about six such risk assessments. We recommend that FDA and EPA examine these risk assessments to determine how reasonable their methodology is, and how their outcomes compare to Federal standards:

We also recommend that the FDA and other relevant agencies determine how quickly they could act to preempt the Proposition 65 warning requirements, should the costs imposed by that statute on non-California persons increase to a level sufficient to justify such action, so that Federal officials can better determine what preemptive action would be necessary when they were presented with certain and sufficiently large harms that clearly call for such action.

Thomas G. Moore
Chairman
Working Group on Proposition 65

Footnotes

1. The FDA has estimated such costs to range from \$100 to \$570 (in 1984 dollars) per product label, depending on the nature of the packages.
2. The Working Group has undertaken a questionnaire survey of approximately 100 major producers of foods, cosmetics, or over-the-counter drugs for the California market concerning their responses to Proposition 65. No results are as yet available from this survey.
3. Hazelton Laboratories, in a study done for The Proprietary Association, estimated that the cost of a full test of a product sample for all listed chemicals, using currently available analytical techniques, would be approximately \$6,000.
4. The higher the elasticity of demand, the smaller the proportion of producer costs that can be passed on to California consumers. Similarly, the lower the elasticity of supply, the smaller the proportion of producer costs that can be passed on to California consumers.
5. A preliminary analysis of Proposition 65 conducted by the Department of Agriculture estimated that only 11 percent of the cost burden of that law will be borne by out-of-state producers rather than California consumers.
6. It seems possible, however, that the courts may rule that quality control measures need only be reasonably effective, rather than perfect, for manufacturers to avoid being found to have "knowingly and intentionally" caused exposures to carcinogens. If so, manufacturers may not be found liable for isolated non-labeled exposures.
7. See Footnote 1, Supra.
8. A preliminary analysis of Proposition 65 conducted by the Department of Agriculture has concluded that only about 11 percent of the cost burden of Proposition 65 will be borne by out-of-state producers, rather than the 35 to 70 percent estimated by Lexecon.
9. There is some question whether the FDA pregnancy nursing warning rules would preempt the application of the reproductive toxin warning requirements to aspirin products.

EXHIBIT D



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

MAY 17 1989

Dr. Frank Young
Commissioner
Food and Drug Administration
5600 Fisher's Lane
Rockville, MD 20857

Dear Frank:

It appears that representatives of the various interests involved in California's Proposition 65, and particularly the food industry, are again seeking opportunities to have their case reheard. I gather that they are visiting a number of departmental and agency officials.

As you know, the Administration has determined that, until there is a significant change in the situation in California with regard to the State's implementation of Proposition 65, which change substantially implicates important Federal interests, no Federal preemptive action - either by regulation or otherwise - is warranted. That position was formally established in the Reagan-Bush Administration, after extensive review by a Working Group of which you were chair; the matter has been revisited by the Bush-Quayle Administration, and this position continues without change.

This office has been assigned responsibility for monitoring the situation, and for ensuring that the Administration is kept informed of important changes that may occur. Conflicting signals about the Administration's position by departmental or agency officials can create false hopes and encourage counterproductive efforts to undermine this carefully considered policy. They can also be a source of potential embarrassment to the President. If you have information that would be of value in our on-going monitoring, I would be pleased to hear of it. In the meantime, we know we can depend on you to protect the Administration's decision against such efforts to undermine it.

Sincerely,

S. Jay Pinger
Administrator
Office of Information
Regulatory Affairs

c: Director Darman
Secretary Sullivan ✓
Under Secretary Horner
Dr. Mason
Associate Director Holen

EXHIBIT E

SUMMARY OF FOOD INDUSTRY LOBBYING ATTEMPTS

(Proposition 65 preemption for foods and related products)

Production date	Federal forum	Description	Outcome
06/06/1988	<u>S. 2468</u>	FDA Revitalization Act. Title VII ("Uniformity in Regulations") would preempt Prop. 65 for FDA-regulated products.	
mid-1988	White House Cabinet-level task force (Reagan Admin)	to consider federal preemption of Prop. 65, at food industry request	reject food industry cost study as "vastly overstated"; reject preemption. See full report .
04/06/1989	<u>H.R. 1725</u>	FFDCA amendments on pesticide residues. "Negligible risk" standard of safety would preempt Prop. 65.	
Spring 1989	U.S. FDA; HHS (early GHW Bush Admin)	renewed food-industry lobbying for FDA to take preemptive action against Prop. 65	<u>OMB directive</u> to maintain "no-preemption" position
07/27/1989	<u>S. 1425/H.R. 3028</u>	Nutrition Labeling and Education Act of 1989. Hatch Amendment ("National Uniform Nutrition Labeling") would preempt Prop. 65 for foods.	
08/03/1989	<u>S. 1505</u>	FFDCA amendments, including "to provide for national uniformity in food labeling."	
05/12/1995	<u>H.R. 1627</u>	FIFRA and FFDCA amendments "State Authority" provision (Section (1)(4)) would preempt Prop. 65.	P.L. 104-170 (08/03/96) [preemption not included]
08/10/1995	<u>S. 1166</u>	FIFRA amendments; Section 305 "State Authority" provision would preempt Prop. 65 for pesticide residues on food.	
03/29/1996	<u>H.R. 3200</u>	FFDCA amendments, Section 108 ("National Uniformity") would preempt Prop. 65 for foods, drugs, and cosmetics.	
05/21/1997	Federal OSHA, U.S. Department of Labor	House Small Business Committee scheduled hearing to pressure Federal OSHA to reject Cal-OSHA incorporation of Prop. 65 into workplace standards (effectively preempting Prop. 65 in the workplace).	Hearing cancelled with witnesses present, 5/21/97. Not rescheduled
06/05/1997	<u>S. 830/H.R. 1411</u>	FDA Modernization Act of 1997 creates "uniformity" for prescription drugs and cosmetics.	P.L. 105-115 (11/21/97) Includes specific <u>exemption</u> from uniformity requirements for Prop. 65.
07/27/1998	<u>S. 2356</u>	National Uniformity for Food Act 1998, "to provide for uniform food safety warning notification requirements, and for other purposes."	
05/27/1999	<u>S. 1155/H.R. 2129</u>	National Uniformity for Food Act of 2000, "to provide for uniform food safety warning notification requirements, and for other purposes."	Last-minute request from Senate Majority Leader to add to HHS Appropriation bill, October 2000; rejected after <u>Senators' letter</u> to President Clinton and <u>Clinton Administration opposition</u> .
10/28/1999	House Committee on Small Business	Hearing to explore preemption of Prop. 65, focused on <u>abuses</u> in citizen enforcement.	Hearing closes with chair noting California's recent amendment to Prop. 65 to address enforcement issues (S.B. 1269).
07/26/2001	<u>H.R. 2649</u>	National Uniformity for Food Act of 2001.	